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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,913	09/25/2003	Matthew S. Solar	50741-000019/US	8466
27572 7590 12/26/2007 HARNESS, DICKEY & PIERCE, P.L.C. P.O. BOX 828 BLOOMFIELD HILLS, MI 48303			EXAMINER TYSON, MELANIE RUANO	
			ART UNIT 3773	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/671,913

Applicant(s)

SOLAR ET AL.

Examiner

Melanie Tyson

Art Unit

3773

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5, 6, 8-20, 22, 23, 25 and 35-47 is/are pending in the application.
- 4a) Of the above claim(s) 8, 10 and 13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 6, 9, 11, 12, 14-20, 22, 23, 25, and 35-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

This action is in response to applicant's amendment received on 23 October 2007.

Claims 8, 10, and 13 remain withdrawn from consideration.

#### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11, 12, 14-16, 38-40, and 43-47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Amended claim 11 recites the limitation "at least one relief opening in a portion of the spherical socket defined by a complete disassociation of at least two portions of the spherical socket" and new claim 38 recites the limitation "wherein the relief openings are defined as a complete passage between at least two members defining the spherical socket of the base." At the time the application was filed, the applicant disclosed a spherical socket that extends through the entire base unit, wherein the relief openings extend from the top of the base unit to the planar portion of the base unit only. The relief openings only disassociate two portions of the top portion of the base unit, not two portions of the spherical socket. Therefore, the subject matter recited in claims 11 and 38 is considered new matter.

New claim 40 recites the limitation "wherein the spherical socket includes at least two members hingedly connected to the first side of the substantially planar portion" and new claim 43 recites the limitation "the at least two fingers are operable to hinge relative to the first portion." At the time the application was filed, the applicant disclosed the top portion of the base unit is deformable, yet failed to disclose the top portion is hingedly connected to or is operable to hinge relative to the planar portion. Therefore, the subject matter recited in claims 40 and 43 is considered new matter.

***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1, 3, 5, 9, and 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henderson et al. (2003/0114752 A1) in view of D'Urso (5,752,962).

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Henderson discloses an alignment device (see entire document) comprising a longitudinal guide portion (424), a spherical portion (528), a base unit (the combination of all 3 base members having opening 1034) having a deformable spherical socket portion (1040), an actuating device including a threaded locking ring (432) surrounding and engaging threads disposed on an outer perimeter of the spherical socket, and a standoff feature (104) adapted to mount directly to a skull of a subject including a shelf (422). Henderson fails to disclose a number of standoff features attached to the base unit.

D'Urso discloses an alignment device (see entire document) comprising a longitudinal guide portion (27), a spherical portion (26), and a base unit (20). D'Urso teaches a number of standoff features (22) to support the base unit above the working space (for example, see Figure 4). It is well within the general skill of one having ordinary skill in the art to substitute a known element for another. Furthermore, it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the standoff feature disclosed by Henderson into a number of standoff features as taught by D'Urso to support the base unit above a work space.

5. Claims 2, 6, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henderson et al. in view of D'Urso as applied to claim 1 above, and further in view of Mowlai-Ashtiani (6,110,182).

Henderson in view of D'Urso fails to disclose relief openings in the spherical socket. Mowlai-Ashtiani discloses an alignment device (see entire document) comprising a guide portion (72), a spherical portion (32), and a deformable socket (10; via attachment 78; column 3, lines 45-51). Mowlai-Ashtiani teaches three relief openings in the spherical socket (for example, see Figure 3). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the spherical socket of Henderson in view of D'Urso having relief openings as taught by Mowlai-Ashtiani. Doing so would allow a user to easily manipulate the socket (for example, see column 3, lines 40-44).

6. Claims 11, 12, 15, 16, 39, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henderson et al. in view of Mowlai-Ashtiani and D'Urso.

Henderson discloses an alignment device (see entire document) comprising a longitudinal guide portion (424), a spherical portion (528), a base unit (the combination of all 3 base members having opening 1034) including a substantially planar portion (1030), wherein a deformable spherical socket portion (1040) extends from a first side, a number of securing devices (screws in mounting holes 416), an actuating device including a threaded locking ring (432) surrounding and engaging threads disposed on an outer perimeter of the spherical socket, and a standoff feature (104) extending from a second side of the planar portion adapted to mount directly to a skull of a subject and having a shelf (422). Henderson fails to disclose at least one relief opening in a portion of the spherical socket and a number of standoff features attached to the base unit.

Mowlai-Ashtiani discloses an alignment device (see entire document) comprising a guide portion (72), a spherical portion (32), and a deformable socket (10; via attachment 78; column 3, lines 45-51). Mowlai-Ashtiani teaches three relief openings in the spherical socket, wherein at least one relief opening is defined by a complete disassociation between two portions (for example, see Figure 3). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the spherical socket of Henderson having relief openings as taught by Mowlai-Ashtiani. Doing so would allow a user to easily manipulate the socket (for example, see column 3, lines 40-44).

D'Urso discloses an alignment device (see entire document) comprising a longitudinal guide portion (27), a spherical portion (26), and a base unit (20). D'Urso teaches a number of standoff features (22) to support the base unit above the working space (for example, see Figure 4). It is well within the general skill of one having ordinary skill in the art to substitute a known element for another. Furthermore, it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the standoff feature disclosed by Henderson into a number of standoff features as taught by D'Urso to support the base unit above a work space.

7. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Henderson in view of Mowlai-Ashtiani and D'Urso as applied to claim 11 above, and further in view of Ghajar et al. (Patent No. 4,998,938). Henderson in view of Mowlai-

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Ashtiani and D'Urso fails to disclose the standoff features are cone shaped. Ghajar discloses an alignment device (see entire document). Ghajar teaches cone shaped standoff features (wider on top and narrower towards the bottom) to support the device above a working space. It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize cone shaped standoff features in the device of Henderson in view of Mowlai-Ashtiani and D'Urso as taught by Ghajar in order to support the base unit (via the large surface area) while minimizing contact with respect to the patient's scalp and cranium (via the smaller surface area) during the procedure, thus reducing the risk of infection to the surrounding tissue (column 2, lines 44-48).

8. Claims 17-20 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henderson et al. and Magee et al. (5,957,927).

Henderson discloses an alignment device (see entire document) comprising a longitudinal guide portion (424), a spherical portion (528), a base unit (the combination of all 3 base members having opening 1034), a deformable spherical socket portion (1040), an actuating device (432), and a standoff feature (104) having a shelf (422) and a passage (416) for an attaching device. Henderson fails to disclose a retention force providing member to retain the attaching device.

Magee discloses a bone fixation device holder (see entire document). Magee teaches a screw retention member (retaining element 62, Figure 10; column 5, lines 31-34) that is located external to, and above screw opening (34) in order to hold the screw while it is initially being driven into bone (for example, see column 5, lines 31-40). It would have been obvious to one having ordinary skill in the art at the time the invention



was made to provide the device of Henderson with retention members as taught by Magee. Doing so would further assist in proper placement and securement of the device.

With further respect to claims 18, 19, and 41, Henderson in view of Magee fails to disclose that the screw retention feature includes an elastomer band or a structure that protrudes into the passage. At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to utilize an elastomer band or a protruding structure to retain the attaching device. There are numerous retention features well known in the art and the applicant failed to disclose that an elastomer band or a protruding structure provides an advantage, is used for a particular purpose, or solves a stated problem. For example, Coates et al. (Patent No. 5,423,826) discloses a structure (Figure 6; O-ring 69 formed of biocompatible elastomeric material, thus comprises an "elastomer band"; column 9, lines 39-40) that protrudes into a portion of a screw opening and is strong enough to resist screw pull out (column 9, lines 33-44). Therefore, it would have been obvious to one of ordinary skill in the art to modify the retention features of Henderson in view of Magee to obtain the invention as specified in claims 18, 19, and 41.

9. Claims 22, 23, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over D'Urso in view of Mowlai-Ashtiani and Hennig (Patent No. 6,328,748).

D'Urso discloses an alignment device (see entire document) comprising a longitudinal guide portion (for example, see Figure 4; element 27), a spherical portion

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(26), a base unit (20), a spherical socket (25), an actuating device (threaded screw 30 comprises a "threaded ring"), three standoff features (21) capable of contacting the work surface (24) along a circle, a shelf (22) having an attachment thickness less than the standoff feature thickness (for example, see Figure 4), a number of securing devices (bone screws in apertures 23), and screw retention features (internal threading of apertures 23). D'Urso fails to disclose that the spherical socket includes relief openings and an insert located within the longitudinal opening.

Mowlai-Ashtiani discloses an alignment device (see entire document) comprising a guide portion (72), a spherical portion (32), a deformable socket (10; via attachment 78; column 3, lines 45-51), and an actuating device (52). Mowlai-Ashtiani teaches the spherical socket (12) contains three relief openings (22; for example, see Figure 2) and the actuating device (52) provides symmetric tightening of the spherical socket (12) around the spherical portion (column 2, lines 15-18 and 50-54). It would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the device of D'Urso such that the spherical socket includes relief openings as taught by Mowlai-Ashtiani. Doing so would allow a user to easily manipulate the device (for example, see column 3, lines 40-44 and column 2, lines 19-27).

Hennig discloses an alignment device (see entire document). Hennig teaches an insert (Figure 5, element 17) located within a longitudinal opening (10). Figure 1 shows the outer diameter is similar to that of the guide (11), thus fits closely with the opening (10). The inner diameter fits closely with a device to be guided ("specially adapted to" column 6, lines 35-36). It would have been obvious to one of ordinary skill in the art at

the time the invention was made to utilize an insert in the device of D'Urso as taught by Hennig in order to size the longitudinal opening in the longitudinal guide with the specific equipment that is to be passed there through (column 6, lines 35-36). Furthermore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to size the insert to fit closely with a biopsy probe since it is well known in the art to utilize probes in surgery (for example, see Mowlai-Ashtiani column 4, lines 31-34).

10. Claims 22 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henderson in view of Mowlai-Ashtiani, D'Urso, and Hennig.

Henderson discloses an alignment device (see entire document) comprising a longitudinal guide portion (424), a spherical portion (528), a base unit (the combination of all 3 base members having opening 1034) including a substantially planar portion (1030), wherein a deformable spherical socket portion (1040) extends from a first side, a number of securing devices (screws), an actuating device including a threaded locking ring (432) surrounding and engaging threads disposed on an outer perimeter of the spherical socket, and a standoff feature (104) extending from a second side of the planar portion adapted to mount directly to a skull of a subject and having a shelf (422) and a passage (416). Henderson fails to disclose at least one relief opening in a portion of the spherical socket, a number of standoff features attached to the base unit, and an insert.

Mowlai-Ashtiani discloses an alignment device (see entire document) comprising a guide portion (72), a spherical portion (32), and a deformable socket (10; via attachment 78; column 3, lines 45-51). Mowlai-Ashtiani teaches at least one relief

opening in the spherical portion (for example, see Figure 3). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the spherical socket of Henderson having at least one relief openings as taught by Mowlai-Ashtiani. Doing so would allow a user to easily manipulate the socket (for example, see column 3, lines 40-44).

D'Urso discloses an alignment device (see entire document) comprising a longitudinal guide portion (27), a spherical portion (26), and a base unit (20). D'Urso teaches a number of standoff features (22) to support the base unit above the working space (for example, see Figure 4). It is well within the general skill of one having ordinary skill in the art to substitute a known element for another. Furthermore, it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the standoff feature disclosed by Henderson into a number of standoff features as taught by D'Urso to support the base unit above a work space.

Hennig discloses an alignment device (see entire document). Hennig teaches an insert (Figure 5, element 17) located within a longitudinal opening (10). Figure 1 shows the outer diameter is similar to that of the guide (11), thus fits closely with the opening (10). The inner diameter fits closely with a device to be guided ("specially adapted to" column 6, lines 35-36). It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize an insert in the device of D'Urso as taught by Hennig in order to size the longitudinal opening in the longitudinal guide with the specific

equipment that is to be passed there through (column 6, lines 35-36). Furthermore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to size the insert to fit closely with a biopsy probe since it is well known in the art to utilize probes in surgery (for example, see Mowlai-Ashtiani column 4, lines 31-34).

11. Claims 43-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henderson et al. in view of Mowlai-Ashtiani and Magee.

Henderson discloses an alignment device (see entire document) comprising a longitudinal guide portion (424), a spherical portion (528), a base unit (the combination of all 3 base members having opening 1034) including a substantially planar portion (1030), wherein a deformable spherical socket portion (1040) extends from a first side, a number of securing devices (screws in mounting holes 416), an actuating device including a threaded locking ring (432) surrounding and engaging threads disposed on an outer perimeter of the spherical socket, and a standoff feature (104) extending from a second side of the planar portion adapted to mount directly to a skull of a subject and having a shelf (422). Henderson fails to disclose at least one relief opening in a portion of the spherical socket and a retaining member.

Mowlai-Ashtiani discloses an alignment device (see entire document) comprising a guide portion (72), a spherical portion (32), and a deformable socket (10; via attachment 78; column 3, lines 45-51). Mowlai-Ashtiani teaches at least one relief opening defined by a complete separation between two portions (for example, see Figure 3). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the spherical socket of Henderson having a relief

opening as taught by Mowlai-Ashtiani. Doing so would allow a user to easily manipulate the socket (for example, see column 3, lines 40-44).

Magee discloses a bone fixation device holder (see entire document). Magee teaches a screw retention member (retaining element 62, Figure 10; column 5, lines 31-34) that is located external to, and above screw opening (34) in order to hold the screw while it is initially being driven into bone (for example, see column 5, lines 31-40). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Henderson with retention members as taught by Magee. Doing so would further assist in proper placement and securement of the device.

### ***Response to Arguments***

12. Applicant's arguments with respect to claims 1-3, 5, 6, 9, 11, 12, and 14-20 have been considered but are moot in view of the new ground(s) of rejection.

13. Applicant's arguments filed 23 October 2007 with respect to claims 22, 23, and 25 have been fully considered but they are not persuasive. Applicant argues primarily that the prior art applied are not properly combined and fail to teach each and every element claimed. Examiner respectfully disagrees.

Applicant argues that Hennig teaches away from any device where a ball center point is located outside of the area defined by the cranium, such as those taught by D'Urso and Mowlai-Ashtiani. However, in the lines cited by the applicant (col. 1, lines 41-45), Hennig simply discusses the disadvantages of utilizing loose screws.

Furthermore, the Hennig reference has been utilized simply for the teaching of including inserts in alignment devices, not for the structure of the alignment device itself.

Applicant further argues that Hennig fails to disclose an insert as claimed, specifically that the insert is not located within the longitudinal opening of the longitudinal guide portion nor is the inner diameter sized to closely fit with a device to be guided. However, Figure 5 clearly shows that the insert (17) is to be inserted into a longitudinal opening (10) and is sized to fit closely with a device to be guided (see dashed lines in spherical portion 2).

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571) 272-9062. The examiner can normally be reached on Monday through Thursday 8:30-7 (max flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson  
December 15, 2007



(JACKIE) TAN-UYEN HO  
SUPERVISORY PATENT EXAMINER